



Mitchell H. Katz, MD
Director of Health

July 8, 2003

Via E-Mail to regulations@ssa.gov

Commissioner, Social Security Administration
P.O. Box 17703
Baltimore, MD 21235-7703

Re: Comments in Response to Social Security Administration's Advance Notice of Proposed Rulemaking on Revised Medical Criteria for Evaluating Immune System Disorders

Dear Madame Commissioner:

The San Francisco Department of Public Health submits these comments in response to the notice of May 12, 2003 regarding the Social Security Administration's (SSA) intention to revise the criteria for evaluating immune system disorders under federal disability programs.

The San Francisco Department of Public Health (SFDPH) is a comprehensive public health care system that provides direct health care services to people living with HIV/AIDS. San Francisco is a large urban area with a deeply entrenched HIV epidemic. As one of the first epicenters of HIV, the City and County of San Francisco has always been at the forefront of the response to the AIDS epidemic. SFDPH is widely recognized as a center of excellence and innovation in AIDS-related public health practice and research. Its hospitals and neighborhood health centers provide primary medical care, specialty care, mental health and substance abuse treatment, case management, and other services to people living with HIV/AIDS. SFDPH is the single largest provider of HIV care in San Francisco. Overall, SFDPH's integrated health care delivery system serves a broad spectrum of San Franciscans, including multiple racial and ethnic groups, the homeless, substance users, people with HIV/AIDS, and the urban poor.

Despite significant advances in treatment, HIV disease remains a progressive, terminal illness for which there is no cure. While new and effective drug regimens, have helped to prolong many lives, they have also proved difficult to follow and sometimes independently disabling. Some individuals find that they do not respond to certain combinations of medications, others are markedly hampered in their daily activities by oppressive side effects, and still others find themselves unable to adhere to the restrictive schedules that the medications mandate. As a result, even with medications potentially available, many people with HIV remain unable to engage in substantial gainful activity. Thus, it is critical that any changes to the immune disorder criteria for disability reflect the complicated nature of this terminal illness. Further, as HIV disease remains a terminal illness, presumptive eligibility for SSI benefits must be preserved.

SFDPH believes that it is crucial that people with HIV disease have a fair and accurate assessment of their disability status, based on up-to-date scientific information. The current

immune system disorder listings could be improved to more fully reflect the complex nature of HIV disease and, thus, ensure appropriate benefits for all people who are truly disabled by HIV disease. To that end, we request that SSA consider the following when revising these criteria:

1 Training and Qualifications

With significant recent and ongoing advances in HIV medicine and treatment, it is essential that medical and administrative staff involved in adjudicating immune disorder disability claims have sufficient training and experience with HIV disease. Because of the complexities inherent in treating HIV disease, the Social Security Administration must rely on staff with sufficient continuous training and experience in HIV disease when revising these immune system disorder listings and when evaluating immune system disorder disability claims at all stages, from initial determination through consultative examinations and the appeals process.

a. Medical Specialists

Disability claims evaluations must be performed by qualified medical specialists who have knowledge of and experience with the most current standards of HIV care. Data indicate that HIV specialists are uniquely prepared to comprehend the intricacies of HIV/AIDS treatments and complex drug regimens. Definitions of HIV/AIDS specialist have been established by at least two independent medical professional societies, the Infectious Disease Society of America and the American Academy of HIV Medicine. These criteria or other comparable training standards would provide an adequate basis for determination of a HIV/AIDS specialist.

b. Administrative Specialists

In addition to medical specialists, it is also imperative that analysts and other staff reviewing disability claims for persons with HIV disease be appropriately trained in the complexities of the disease and how disease manifestations meet listing level impairments. This is particularly true in areas of the country where there is a concentration of HIV infection, such as in San Francisco. We recognize and appreciate efforts in California to effectively track HIV cases by centralizing Bay Area HIV claims out of the State's Disability and Adult Program Division. This allows staff to become experienced with the multiple and unique issues facing persons with HIV disease. However, we believe that these offices could benefit from additional training on HIV treatment and the wide range of health symptoms and side effects experienced by persons with HIV. The Department of Health and Human Services currently supports 18 AIDS Education and Training Centers (AETC) throughout the country and that should be used to provide the administrative specialist training in HIV.

2. Impact of Medications on People with HIV

The criteria for evaluating immune disorders should include a detailed discussion of the wide range of responses to medication experienced by people with HIV. As discussed above, HIV medication regimens do not always induce an effective response against

HIV. Even when the drugs are effective, they are often difficult to adhere to and in some instances, even when used accurately, inflict physical symptoms that are independently disabling.

a. Symptoms vs. Side Effects

The SSA criteria should reflect that distinguishing repeated manifestations as either symptoms of HIV disease or side effects of medication is immaterial to a determination of disability. Because many side effects of medication are similar or identical to the symptoms of HIV disease, such as chronic diarrhea, fatigue, nausea, vomiting, or memory loss, it is often difficult or impossible to determine the cause of these symptoms. Further, because it is likely that persons with HIV/AIDS will need to take multiple medications for the rest of their lives, there should be no need to characterize any medication-induced manifestations as “side effects.” As HIV/AIDS remains a terminal illness, persons with HIV have little choice but to continue to take these medications in order to stay alive. Without medications, it is likely that other, equally disabling manifestations of HIV disease would result from a rapid deterioration in health and progression of disease. Thus, the manifestations, regardless of their source, must be considered part of the disability assessment of Step 3 and, to ensure that correct consideration is done at this step, the listing level impairments must be expanded/modified in consultation with a panel of medical HIV/AIDS specialists.

b. Noncompliance

The criteria for determining disability should not penalize persons who have difficulty adhering to the strict regimen of HIV medications. HIV treatment regimens can be extremely complex, often requiring dozens of pills each day that may or may not require refrigeration to be taken at different times with or without food. Just understanding the complex and often contradictory requirements of medication compliance creates significant challenges. Persons in unstable housing and/or with mental illness are put at an even greater disadvantage. Because of these extraordinary difficulties, SSA criteria should acknowledge and explain the complications of medication compliance.

c. Structured Treatment Interruptions and Drug Holidays

The SSA criteria should recognize that structured treatment interruptions and drug holidays under the supervision of a physician are valid forms of long-term treatment for HIV disease. There are several medically valid reasons that treatment may be interrupted. Some persons who started treatment as soon as they were infected may benefit from a boost in the immune system with a break in treatment. Since treatment guidelines continue to change, some people currently on medication may no longer be advised to take medications based upon more recent medical knowledge and standards. Additionally, overwhelming side effects may be another reason that physicians may recommend drug holidays.

3. CD4 and Viral Load

SSA should not rely on CD4 counts and viral loads to determine an applicant's disability or functional capacity. Recent medical research shows that CD4 count and viral load may not be accurate indicators of a patient's degree of resistance to treatment, functional capacity or likelihood of recovery. Often, in practice, when persons with high CD4 counts and low or undetectable viral loads have applied for disability benefits, they have been characterized as not susceptible to opportunistic infections. Others in the opposite situation, with low CD4 counts and high viral load levels have been deemed non-compliant with treatment. However, viral load and CD4 counts can and do change frequently for a variety of reasons, making them unreliable indicators of wellness or disability. Persons with HIV/AIDS are experiencing increasing instances of resistance to the medications, despite adherence, and replication or mutation of the virus, despite medication, causing changes in their CD4 and viral load counts. Further, viral load testing only measures the amount of virus in a person's blood and does not measure the amount of virus that may be hiding in reservoirs, such as: lymph nodes; organs; resting or inactive CD4 cells; or "Natural Killer" cells where replication does not stop even when the viral load reading is undetectable. In addition, the mitochondria effect shows people whose immune systems have been profoundly affected by HIV/AIDS do not regenerate a fully functioning CD4 cells or a working immune system.

4. Stand-alone Conditions

Maintaining the current list stand-alone diagnoses of opportunistic infections in the listing of impairments is critical to ensuring appropriate access to disability benefits for persons with HIV. Despite progress in HIV medications since the listings were promulgated in 1993, diagnosis with one of the stand-alone conditions currently contained in the listings continues to demonstrate that an individual has a severely compromised immune system with a valid presumption of marked functional limitations. Furthermore, while some of the stand-alone diagnoses have become less prevalent since the listings were devised, there are additional diagnoses that warrant addition to that list, such as co-infection with Hepatitis C and chronic or acute pancreatitis. The SSA should seek the advice of a panel of medical HIV/AIDS specialists for additional diagnoses that may be appropriate to add to the listing of impairments.

5. Repeated Manifestations

The category of impairments currently provides for certain repeated manifestations of HIV infection. However, these repeated manifestations should be expanded and more clearly defined to reflect the wider range of symptoms that, whether recurrent or in combination with other symptoms, impair the functional capacity of a person with HIV. As an example, fatigue is a medically valid manifestation of HIV that warrants additional explanation and consideration to better enable persons adjudicating disability claims to appropriately assess the disabling effect of this significant symptom of HIV disease. Additional manifestations include lipid disorders, diabetes mellitus, symptomatic hyperlactatemia (or lactic acidosis), metabolic abnormalities, infarction and cardiac problems, nausea, vomiting, memory loss, concentration problems, cognitive processing difficulties, headaches and insomnia. The SSA should seek the advice of a panel of

medical HIV/AIDS specialists for additional manifestations that may be appropriate to add to the listing of impairments.

6. HIV and Mental Illness

The revised criteria for evaluating HIV-related disability should address the unique challenges associated with a co-diagnosis of mental illness. Not only are persons with mental illness at higher risk for HIV infection, but also once infected, their mental illness often contributes to the progression of HIV disease and the deterioration of physical health. For many people, having a mental illness means unstable housing situations, limited family and social support, disruptions in everyday functioning, and symptoms of anxiety, stress and/or depression, all of which interfere with the ability to care for oneself and to adhere to complicated medication regimens. In addition, the virus itself actually causes mental impairment or dementia in some people (further complicating treatment for both mental illness and HIV disease), along with manifestations such as anxiety disorder and clinical depression (which may render persons unable to work).

7. HIV and Substance Abuse

Currently, SSA criteria provide that the materiality of substance abuse as a disabling factor must be reviewed to assess disability. However, because this standard is not uniformly enforced, the regulations may warrant additional discussion of the interaction between HIV disease and substance abuse to enable claims analysts to better assess materiality of substance use. For example, some of the symptoms HIV/AIDS, such as wasting syndrome and fatigue, may appear to be similar to symptoms of substance use but are, in fact, repeated symptoms of HIV/AIDS.

8. Duration of HIV/AIDS Impairment

The SSA criteria must clarify that a determination of disability is primarily based upon the person's HIV/AIDS diagnosis in addition to one or more other diagnoses or manifestations of HIV that taken together result in functional impairment. Recovery from one or more of these additional diagnoses may or may not result in increased functional capacity to work, but does not automatically do so and, therefore, should not automatically preclude a continued finding of disability. The underlying diagnosis of HIV/AIDS may continue to cause severe functional limitations as a result of the continued deterioration of the individual's immune system. Thus, in these situations, a complete review of the patient's medical evidence must be made by a HIV/AIDS specialist before any determination of restored functional capacity is made. Further, the assessment of the treating physician or medical provider should be given substantial weight in this determination.

9. Laboratory Evidence of the Manifestations of HIV Disease

The SSA criteria should be modified to reflect advances in medical diagnostic procedures and increased knowledge of the clinical manifestations of HIV disease that, in many cases, eliminate the need for laboratory evidence of certain HIV-related conditions. Many conditions are now commonly diagnosed by assessing their clinical manifestations,

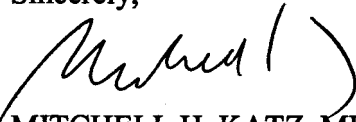
presumptive criteria, and treatment responses, rather than through laboratory procedures. Esophageal candidiasis, for example, is diagnosed by a physician as a result of his/her observation, training, and experience, rather than through clinical testing, which is no longer part of standard medical practice for this condition. Revisions to the listings should reflect these advances.

10. Return to Work

In addition to seeking recommendations on the listing of impairments criteria, the Notice of Proposed Ruling solicits recommendations for improving work incentives for persons with immune disorders who want to work full- or part-time with supports. The Ticket to Work and Work Incentives Improvement Act did much to improve the Work Incentive regulations, especially in extending Medicare benefits for several years after a successful return to work, and in guaranteeing expedited reinstatement to disability claims. However, there are additional system improvements that could be made to further encourage and enable persons with HIV to maintain current employment and avoid disability or return to gainful employment. Chief among these improvements is an increased effort by SSA to ensure that staff at all levels have a full and complete understanding of the Act and its relation to the work and services performed by SSA (e.g. suspension of disability reviews, establishment of trained work incentives specialist within SSA, etc.).

Thank you for your consideration of our comments. SFDPH looks forward to receiving additional information about the Notice of Proposed Rulemaking as it becomes available. Please contact Colleen Johnson, Assistant Director of Policy and Planning, at my address with notification of additional actions related to this issue. She may also be reached at telephone number (415) 554-2633, fax number, (415) 554-2622 or e-mail at colleen.johnson@sfdph.org.

Sincerely,



MITCHELL H. KATZ, MD
Director of Health